

VAMHCS Research Service

GUIDANCE FOR DEVELOPING A “VA-UM COLLABORATIVE PROTOCOL” (To be used in conjunction with “Investigator Tool for VA-UM Collaborative Protocol”)

Investigators holding dual-appointments¹ with the University of Maryland and the VA Maryland Health Care System (VAMHCS) are required to clearly separate VA (VAMHCS) research from affiliate (UM) research. This is a requirement from VHA Office of Research Oversight.²

This may entail designing protocols so that there are two separate protocols (one for UM activities and one for VA activities) or designing a single protocol that clearly defines the research activities that are conducted on VA v. UM time, resources, etc.

To assist in this effort, please read carefully and follow the instructions provided below. This document contains the following sections:

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¹ Currently most VAMHCS principal investigators must hold a full-time University of Maryland Baltimore faculty appointment unless this requirement has been waived by the University Institutional Official (IO). Some PIs on VA Central IRB studies do not have UM appointments.

² [IMPLEMENTATION UPDATE ON July 2011 Interim Guidance on Research Data Disclosures for “Collaborative” Studies December 12, 2011](#)

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1. General Decisions and Considerations

- a. **STOP HERE** if your study is “completely VA” research or “completely UM” research.
 - VA Research: all research activities are conducted at VA or VA-leased space, on VA paid time or duty time, using only VA resources, or entirely VA-funded.
 - There should be NO University informed consent form or HIPAA authorization.
 - There should be no research disclosures to the UM (no release of PHI or other information to the University).
 - Both the informed consent form and HIPAA authorization should clearly reflect this information (there should be no research disclosures to the UM, etc.).
 - The study must be submitted to the VA R&D Committee promptly after receiving IRB approval.
 - The study cannot be initiated until you have received notification from the VAMHCS ACOS/R&D.
 - UM Research: all research activities are conducted at the University, on UM paid time, using only UM resources.
- b. **CONTINUE** if your study is “VA-UM Collaborative” research: research activities are conducted at **both VAMHCS** (at VA or VA-leased space, on VA time, using VA resources) **and UM** (at UM, on UM time, using UM resources).
 - Decide whether you should design two separate studies or a single study with VA vs. UM activities clearly defined.
 - If you decide to design **two separate studies**, a “VA-only” study and a “UM-only” study. The UM study would go through the IRB as a “UM-only study” and the VA study would go through the IRB and VA R&D Committee as a “VA-only” protocol. (See I.1.a above). You would then have two protocols to maintain for continuing review, modifications, etc. Each protocol would have informed consent forms (ICF) and HIPAA authorizations that would be specific to the actual activities to be done at the sites and, as relevant, would describe to the participant that there is a related protocol at the VA/UM at which various activities will take place. You would still need to make decisions about how the data will be combined and the assignment of a “local coordinating center” (see I.2 below). Examples of circumstances where **two separate studies** could be the better option:
 - If the study involves some activities that occur at the VAMHCS and others that occur at the University, consider whether you could design one protocol for the VAMHCS and another protocol for the UM. The VAMHCS ICF and HIPAA authorization would describe the VAMHCS activities but would also need to mention the related UM study for

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which the participant is also being recruited. VA information security and privacy requirements must be met (disclosures of information, data use agreements, etc.)

- If the interventions occur at the UM but the data analysis, specimen storage, etc. occur at the VAMHCS/VA-leased space, you could design a “data analysis-only” protocol, “specimen-banking protocol”, etc. specifically for the VAMHCS. The VAMHCS ICF and HIPAA authorization would describe the VAMHCS activities but would also need to mention the related UM study. VA information security and privacy requirements must be met (disclosures of information, data use agreements, deidentification, etc.)
- There are other scenarios.

It is recommended that you review the [PI Tool For VA-UM Collaborative Studies](#), [Decision Flowchart for VA-UM Collaborative Studies](#), an ‘activities-locations’ table, and the [VAMHCS Reviewer Guide for Separation of VA vs. Non-VA Research](#) as a check on whether you have divided the protocols completely.

- If you decide to design a **single protocol in which the VA and UM activities are clearly defined**, you would use the study protocol/CICERO submission to define the activities, and you would have distinct ICFs and HIPAA authorizations for the VA and UM components of the protocol. The VAMHCS ICF and HIPAA authorization would be specific to the VA-related activities and, as relevant, would mention the related protocol at the UM at which various activities will take place; the UM ICF and HIPAA authorization would do the same. The participant would sign both ICFs and both HIPAA authorizations. You must decide how the data will be combined and the assignment of a “local coordinating center” (see I.2 below). Use the [PI Tool For VA-UM Collaborative Studies](#), [Decision Flowchart for VA-UM Collaborative Studies](#), an ‘activities-locations’ table, and the [VAMHCS Reviewer Guide for Separation of VA vs. Non-VA Research](#). At continuing review, you would need to clarify your enrollment numbers in the CICERO report (so that one participant does not get counted as both a VA and a UM participant, potentially doubling your numbers).

2. “VA-UM Collaborative Protocols”

- a. If you do have a “VA-UM Collaborative Protocols”, decide whether you intend to combine the data obtained from both the VA and UM sites/activities.
- b. If you do decide to combine the data, you must decide which site (VA or UM) will be the “**local coordinating center**”. The “local coordinating center” is the site where data will be received, analyzed and stored.
- c. IF the **UM/Collaborator** is the Local Coordinating Center holding the “combined data set”, the dual-appointed investigator cannot use the combined data set while

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on VA time unless it is approved as an “off-site” VA research activity in consultation with ORD and Regional Counsel. In practical terms, if you wish to designate the UM as the local coordinating center, you should be prepared to provide documentation of your non-VA time. It is unclear how quickly a decision from VA ORD and Regional Counsel can be obtained.

- d. IF the **VAMHCS** is the Local Coordinating Center holding the “combined data set”, you must describe the interaction/intervention and data collection activities at the VAMHCS site and describe the activities of the VAMHCS Local Coordinating Center in receiving and combining the data from the UM/collaborator site.
 - e. There are general requirements for “VA-UM Collaborative Protocols”:
 - i. The VAMHCS informed consent form, HIPAA authorization and applicable sections of the study protocol / CICERO application have additional requirements for “VA-UM Collaborative Protocols”.
 - ii. Use the documents described in the following sections of this Guidance.
3. Instructions for completing a protocol submission for a “VA-UM Collaborative Protocol”
- a. General Instructions
 - i. Use these instructions to create your protocol(s) in CICERO.
 - ii. The Research Service has provided the following to assist you in this process:
 - [*PI Tool For VA-UM Collaborative Studies*](#)
 - [*Decision Flowchart for VA-UM Collaborative Studies*](#)
 - [*VAMHCS Reviewer Guide for Separation of VA vs. Non-VA Research*](#)
 - [*VA ORO Suggested Activities Table for VA vs. Non-VA Research*](#)
 - [*VAMHCS Informed Consent Template*](#)
 - [*VAMHCS HIPAA Authorization Template*](#)
 - Personal consultation with Research Service by appointment and as staffing allows
 - Additional assistance will be developed as needed.
 - iii. You must use the [*PI Tool for VA-UM Collaborative Studies*](#). Complete the tool (see I.3.b below) and upload it into the “Additional Documents” section of CICERO.
 - iv. In addition to the Tool, you have the following options for documentation of your “VA-UM Collaborative Protocol” or a combination of methods, as practical for your study design.
 - Clearly describe VA/UM activities in the “Procedures”, “Data Analysis”, and other sections of CICERO;
 - Provide an ‘Activities-Locations’ table in your submission or separate activities tables by site. Use an adapted CICERO activities table, the [*VA ORO Suggested Activities Table for VA vs. Non-VA Research*](#), or your own format to depict locations of research activities.

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- Use the [VAMHCS Reviewer Guide for Separation of VA vs. Non-VA Research](#) to guide you in designing your protocol and writing your submission materials.
- v. Design the protocol to encompass the following:
 - Ensure that the protocol clearly separates the activities constituting **VA research** from the activities constituting the **affiliate/collaborator research**.
 - Clearly describe which study procedures are conducted **in VA space, on VA time, using VA resources, VA funding, etc.** (including location of collection and storage of data, access and use, statistical analyses, and security measures).
 - Identify any VA research activities occurring at non-VA sites (i.e., at non-VA properties).
 - “Research related procedures” includes the location of collection and storage, access and use, statistical analyses, and security measures.
 - If the protocol involves data collected in non-VA research (i.e., not collected by VA investigators serving on compensated, WOC, or IPA appointments while on VA time, utilizing VA resources, or on VA property including space leased to, or used by VA), explain how non-VA activities and data are separated from VA activities and data.
- b. Specific Instructions for completing the [PI Tool For VA-UM Collaborative Studies](#):
 - i. Read the footnotes for assistance on particular items.
 - ii. If the requested information is already documented somewhere else (such as in CICERO, on the ISO/PO checklist, in an ‘activities-locations table’, elsewhere in the template), do not re-write. Simply state where the information can be found by a reviewer.
 - iii. Describe all research activities and locations (some specific topics are covered later in this template). If this has been done in CICERO, state the section(s) of CICERO below. If you have supplemental information, state it below. If you have developed an ‘activities-locations’ table(s), state this below and upload the table(s) into CICERO

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4. Instructions for completing an informed consent form for a “VA-UM Collaborative Study”
 - a. Use the current [VAMHCS Informed Consent Template](#) (revised 10/30/12). Read through the prompts and comments carefully in order to design your VA ICF correctly. It is NOT simply a form where you can copy-paste from the UM ICF.
 - b. Ensure that the ICF
 - i. Only includes the activities that will be done at the VA/on VA time/etc. (with mention of the UM activities when relevant) **OR** clearly defines which activities will be done at the VA and which will be done at the UM.
 - ii. States that:
This is a “collaborative” study that will combine VA research activities and data with University of Maryland research activities and University of Maryland data.
 - iii. *(If UM is the local coordinating center)* states that:
The data will be disclosed to the UM (Coordinating Center) where the data will be combined and analyzed for the “collaborative” study.
 - iv. (if applicable) explains if there will be disclosure of “individually identifiable information” (III) as well as PHI
 - v. States any anticipated use/disclosure for future use
 - vi. Is consistent w the HIPAA authorization, the protocol & the CRADA (if applicable)
 - c. Where applicable, add an ‘Activities-Locations’ table. Or separate activities tables by site.
5. Instructions for completing a HIPAA authorization for a “VA-UM Collaborative Study”
 - a. Use the current [VAMHCS HIPAA Authorization Template](#).
 - b. Ensure that the HIPAA authorization
 - i. Makes it clear that ‘data or results obtained from this study are to be used in a multi-site study that combines VA data with UM data’
 - ii. States where the PHI will be used (UM, VAMHCS, both)
 - iii. States where the PHI will be disclosed (UM entities)
 - iv. *(If UM is the coordinating center)* makes it clear that:
The data will be disclosed to the UM (Coordinating Center) where the data will be combined and analyzed for the “collaborative” study.
 - v. Is consistent w the ICF, the protocol & the CRADA (if applicable).